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Applicant(s)	Shults et al.	Examiner:	Unassigned
Serial No.:	09/916,858	Group Art Unit:	1744
Confirmation No.:	1611	Docket:	1146-4 DIV/CIP II
Filed:	July 27, 2001	Dated:	January 11, 2002
For:	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS		

Commissioner for Patents  
Washington, DC 20231

*I hereby certify this correspondence is being deposited with the United States Postal Service as first class mail, postpaid in an envelope, addressed to: Commissioner for Patents, Washington, D.C. 20231*  
Date: January 11, 2002  
Signature: Linda J. Scheurle *Linda J. Scheurle*

INFORMATION DISCLOSURE STATEMENT

Sir:

In fulfillment of the requirements of candor and good faith set forth in 37 C.F.R. §1.56, Applicant submits herewith the following Information Disclosure Statement in accordance with the provisions of 37 C.F.R. §1.97 and 1.98.

As this Information Disclosure Statement is being filed with the applicant and before the issuance of the first Office Action, no fee is deemed necessary.

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# I. U.S. PATENTS

<u>U.S. PATENT NO.</u>	<u>TITLE</u>	<u>ISSUE DATE</u>
*4,353,888 to Sefton	Encapsulation of Live Animal Cells	October 12, 1982
*4,431,004 to Bessman et al.	Implantable Glucose Sensor	February 14, 1984
*4,436,094 to Cerami	Monitor for Continuous in Vivo Measurement of Glucose Concentration	March 13, 1984
*4,453,537 to Spitzer	Apparatus for Powering a Body Implant Device	June 12, 1984
*4,484,987 to Gough	Method and Membrane Applicable to Implantable Sensor	November 27, 1984
*4,686,044 to Behnke et al.	Polycarbonate-Polyether-Copolymer Membrane	August 11, 1987
*4,703,756 to Gough et al.	Complete Glucose Monitoring System with an Implantable, Telemetered Sensor Module	November 3, 1987
*4,757,022 to Shults et al.	Biological Fluid Measuring Device	July 12, 1988
4,759,828 to Young et al.	Glucose Electrode and Method of Determining Glucose	July 26, 1988
*4,787,398 to Garcia et al.	Glucose Medical Monitoring System	November 29, 1988
*4,803,243 to Fujimoto et al.	Block-Graft Copolymer	February 7, 1989
*4,823,808 to Clegg et al.	Method for Control of Obesity, Overweight and Eating Disorders	April 25, 1989
4,890,620 to Gough	Two-Dimensional Diffusion Glucose Substrate Sensing Electrode	January 2, 1990

<u>U.S. PATENT NO.</u>	<u>TITLE</u>	<u>ISSUE DATE</u>
*4,902,294 to Gosserez	Implantable Mammary Prosthesis Adapted to Combat the Formation of Retractile Shell	February 20, 1990
*4,994,167 to Shults et al.	Biological Fluid Measuring Device	February 19, 1991
5,165,407 to Wilson et al.	Implantable Glucose Sensor	November 24, 1992
*5,190,041 to Palti	System for Monitoring and Controlling Blood Glucose	March 2, 1993
*5,314,471 to Brauker et al.	Tissue Implant Systems and Methods for Sustaining Viable High Cell Densities Within a Host	May 24, 1994
*5,321,414 to Alden et al.	Dual Polarization Dipole Array Antenna	June 14, 1994
5,322,063 to Allen et al.	Hydrophilic Polyurethane Membranes for Electrochemical Glucose Sensors	June 21, 1994
*5,344,454 to Clarke et al.	Closed Porous Chambers for Implanting Tissue in a Host	September 6, 1994
*5,380,536 to Hubbell et al.	Biocompatible Microcapsules	January 10, 1995
5,390,671 to Lord et al.	Transcutaneous Sensor Insertion Set	February 21, 1995
5,391,250 to Cheney, II et al.	Method of Fabricating Thin Film Sensors	February 21, 1995
*5,417,395 to Fowler et al.	Modular Interconnecting Component Support Plate	May 23, 1995
*5,421,923 to Clarke et al.	Ultrasonic Welding Horn with Sonics Dampening Insert	June 6, 1995
*5,431,160 to Wilkins	Miniature Implantable Refillable Glucose Sensor and Material Therefor	July 11, 1995

<u>U.S. PATENT NO.</u>	<u>TITLE</u>	<u>ISSUE DATE</u>
*5,453,278 to Chan et al.	Laminated Barriers for Tissue Implants	September 26, 1995
*5,462,064 to D'Angelo et al.	Integrated System for Biological Fluid Constituent Analysis	October 31, 1995
*5,469,846 to Khan	Implantable Non-Enzymatic Electrochemical Glucose Sensor	November 28, 1995
*5,476,094 to Allen et al.	Acrylic Copolymer Membranes for Biosensors	December 19, 1995
*5,497,772 to Schulman et al.	Glucose Monitoring System	March 12, 1996
5,538,511 to Van Antwerp	Indwelling Catheter with Stable Enzyme Coating	July 23, 1996
*5,545,223 to Neuenfeldt et al.	Ported Tissue Implant Systems and Methods of Using Same	August 13, 1996
*5,549,675 to Neuenfeldt et al.	Method for Implanting Tissue in a Host	August 23, 1996
5,569,186 to Lord et al.	Closed Loop Infusion Pump System with Removable Glucose Sensor	October 29, 1996
*5,569,462 to Martinson et al.	Methods for Enhancing Vascularization of Implant Devices	October 29, 1996
*5,578,463 to Berka et al.	Heterologous Polypeptides Expressed in Filamentous Fungi, Processes for Making Same, and Vectors for Making Same	November 26, 1996
*5,593,440 to Brauker et al.	Tissue Implant Systems and Methods for Sustaining Viable High Cell Densities Within a Host	January 14, 1997
*5,653,756 to Clarke et al.	Closed Porous Chambers for Implanting Tissue in a Host	August 5, 1997
*5,660,163 to Schulman et al.	Glucose Sensor Assembly	August 26, 1997

<u>U.S. PATENT NO.</u>	<u>TITLE</u>	<u>ISSUE DATE</u>
*5,713,888 to Neuenfeldt et al.	Tissue Implant Systems	February 3, 1998
*5,733,336 to Neuenfeldt et al.	Ported Tissue Implant Systems and Methods of Using Same	March 31, 1998
*5,741,330 to Brauker et al.	Close Vascularization Implant Material	April 21, 1998
5,777,060 to Van Antwerp	Silicon-Containing Biocompatible Membranes	July 7, 1998
*5,782,912 to Brauker et al.	Close Vascularization Implant Material	July 21, 1998
*5,800,529 to Brauker et al.	Close Vascularization Implant Material	September 1, 1998
*5,807,406 to Brauker et al.	Porous Microfabricated Polymer Membrane Structures	September 15, 1998
*5,882,354 to Brauker et al.	Close Vascularization Implant Material	March 16, 1999
5,882,494 to Van Antwerp	Polyurethane/Polyurea Compositions Containing Silicone for Biosensor Membranes	March 16, 1999
*5,964,261 to Neuenfeldt et al.	Implantation Assembly	October 12, 1999
5,985,129 to Gough et al.	Method for Increasing the Service Life of an Implantable Sensor	November 16, 1999
6,001,067 to Shults et al.	Device and Method for Determining Analyte Levels	December 14, 1999
*6,122,536 to Sun et al.	Implantable Sensor and System for Measurement of Control of Blood Constituent Levels	September 19, 2000
*6,144,869 to Berner et al.	Monitoring of Physiological Analytes	November 7, 2000

<b><u>U.S. PATENT NO.</u></b>	<b><u>TITLE</u></b>	<b><u>ISSUE DATE</u></b>
6,175,752 B1 to Say et al.	Analyte Monitoring Device and Methods of Use	January 16, 2001
6,180,416 B1 to Kurnik et al.	Method and Device for Predicting Physiological Values	January 30, 2001
6,200,772 B1 to Vadgama et al.	Modified Polyurethane Membrane Sensors and Analytical Methods	March 13, 2001
*6,201,980 B1 to Darrow et al.	Implantable Medical Sensor System	March 13, 2001
*6,208,894 B1 to Schulman et al.	System of Implantable Devices for Monitoring and/or Affecting Body Parameters	March 27, 2001
*6,212,416 B1 to Ward et al.	Device for Monitoring Changes in Analyte Concentration	April 3, 2001
*6,223,080 B1 to Thompson	Power Consumption Reduction in Medical Devices Employing Multiple Digital Signal Processors and Different Supply Voltages	April 24, 2001
*6,223,083 B1 to Rosar	Receiver Employing Digital Filtering for Use with an Implantable Medical Device	April 24, 2001
*6,230,059 B1 to Duffin	Implantable Monitor	May 8, 2001
*6,233,471 B1 to Berner et al.	Signal Processing for Measurement of Physiological Analysis	May 15, 2001
*6,254,586 B1 to Mann et al.	Method and Kit for Supplying a Fluid to a Subcutaneous Placement Site	July 3, 2001
*6,256,522 B1 to Schultz	Sensors for Continuous Monitoring of Biochemicals and Related Method	July 3, 2001
*6,259,937 to Schulman et al.	Implantable Substrate Sensor	July 10, 2001
6,272,364 B1 to Kurnik	Method and Device for Predicting Physiological Values	August 7, 2001

<u>U.S. PATENT NO.</u>	<u>TITLE</u>	<u>ISSUE DATE</u>
6,272,382 B1 to Faltys et al.	Fully Implantable Cochlear Implant System	August 7, 2001
6,299,578 B1 to Kurnik et al.	Methods for Monitoring a Physiological Analyte	October 9, 2001
6,309,351 B1 to Kurnik et al.	Methods for Monitoring a Physiological Analyte	October 30, 2001
6,326,160 B1 to Dunn et al.	Microprocessors for Use in a Device for Predicting Physiological Values	December 4, 2001
6,329,161 B1 to Heller et al.	Subcutaneous Glucose Electrode	December 11, 2001

## II. FOREIGN PATENT DOCUMENTS

<u>PATENT NO.</u>	<u>COUNTRY</u>	<u>ISSUE DATE</u>
*WO 90/00738	PCT	January 25, 1990
*WO 92/07525	PCT	May 14, 1992
*WO 92/13271	PCT	August 6, 1992
WO 93/19701	PCT	October 14, 1993
*WO 94/22367	PCT	October 13, 1994
*WO 96/01611	PCT	January 25, 1996
*WO 96/32076	PCT	October 17, 1996
*WO 96/36296	PCT	November 21, 1996
WO 01/20019 A2	PCT	March 22, 2001
WO 01/20334 A1	PCT	March 22, 2001
WO 01/34243 A1	PCT	May 17, 2001

<u>PATENT NO.</u>	<u>COUNTRY</u>	<u>ISSUE DATE</u>
WO 01/58348 A2	PCT	August 16, 2001
WO 01/68901 A2	PCT	September 20, 2001
WO 01/69222 A2	PCT	September 20, 2001
WO 01/88524 A1	PCT	November 22, 2001
WO 01/88534 A2	PCT	November 22, 2001

### III. NON-PATENT DOCUMENTS

- \*1. Updike et al., "Laboratory Evaluation of New Reusable Blood Glucose Sensor," *Diabetes Care*, 11:801-807 (1988).
- \*2. Moatti-Sirat et al., "Towards Continuous Glucose Monitoring: In Vivo Evaluation of a Miniaturized Glucose Sensor Implanted for Several Days in Rat Subcutaneous Tissue," *Diabetologia* 35:224-30 (1992).
- \*3. Armour et al., "Application of Chronic Intravascular Blood Glucose Sensor in Dogs," *Diabetes* 39:1519-26 (1990).
- \*4. Woodward, "How Fibroblasts and Giant Cells Encapsulate Implants: Considerations in Design of Glucose Sensor," *Diabetes Care* 5:278-281 (1982).
- \*5. Bindra et al., "Design and In Vitro Studies of a Needle-Type Glucose Sensor for Subcutaneous Monitoring," *Anal. Chem.* 63:1692-96 (1991).
- \*6. Shults et al., A Telemetry-Instrumentation System for Monitoring Multiple Subcutaneously Implanted Glucose Sensors, *IEEE Trans, Biomed. Eng.* 41:937-942 (1994).
- \*7. Phillips and Smith, "Biomedical Applications of Polyurethanes: Implications of Failure Mechanisms," *J. Biomat. Appl.* 3:202-227 (1988).
- \*8. Stokes, "Polyether Polyurethanes: Biostable or Not?," *J. Biomat. Appl.* 3:228-259 (1988).
- \*9. Updike et al. Enzymatic Glucose Sensors: Improved Long-Term Performance In Vitro and In Vivo, *Am. Soc. Artificial Internal Organs* 40:157-163 (1994).
- \*10. Updike et al., Implanting the Glucose Enzyme Electrode: Problems, Progress, and Alternative Solutions," *Diabetes Care* 5:207-21 (1982).



- \*11. Rhodes et al., "Prediction of Pocket-Portable and Implantable Glucose Enzyme Electrode Performance from Combined Species Permeability and Digital Simulation Analysis," *Anal. Chem.* 66:1520-1529 (1994).
- \*12. Tse and Gough, Time-Dependent Inactivation of Immobilized Glucose Oxidase and Catalase, *Biotechnol. Bioeng.* 29:705-713 (1987).
- \*13. Gilligan et al., "Evaluation of a Subcutaneous Glucose Sensor Out to 3 Months in a Dog Model," *Diabetes Care* 17:882-887 (1994).
- \*14. McKean and Gough, "A Telemetry-Instrumentation System for Chronically Implanted Glucose and Oxygen Sensors," *IEEE Trans. Biomed. Eng.* 35:526-532 (1988).
- \*15. Shichiri et al., "Telemetry Glucose Monitoring Device with Needle-Type Glucose Sensor-A Useful Tool for Blood Glucose Monitoring in Diabetic Individuals," *Diabetes Care* 9:298-301 (1986).
- \*16. Lyman, "Polyurethanes. I. The Solution Polymerization of Diisocyanates with Ethylene Glycol," *J. Polymer Sci.* 45:49 (1960).
- \*17. DuPont<sup>1</sup> Dimension AR® (Catalog).
- \*18. Direct 30/30® meter (Markwell Medical) (Catalog).
- \*19. Fischer et al., "Oxygen Tension at the Subcutaneous Implantation Site of Glucose Sensors," *Biomed. Biochem.* 11/12, 965-972 (1989).
- \*20. Brauker et al., "Neovascularization of Synthetic Membranes Directed by Membrane Microarchitecture," *Journal of Biomedical Materials Research* 29:1517 (1995).
- \*21. Abstract presented by James Brauker, Ph.D., "Neovascularization of Cell Transplantation Devices: Membrane Architecture-Driven and Implanted Tissue-Driven Vascularization," Baxter Healthcare Corp.
- \*22. Brauker et al., "Local Inflammatory Response Around Diffusion Chambers Containing Xenografts", *Transplantation*, Vol. 61, 1671-1677, No. 12, June 27, 1996.

References denoted by an asterisk (\*) have been previously cited in related application, U.S. Serial No. 09/636,369, filed August 11, 2000. Accordingly, the Examiner is invited to refer to such related application for copies of each of the references. Copies of references not previously cited are submitted herewith.

All of the references listed above are also listed on Applicant's Form PTO-1449 which is attached to this Information Disclosure Statement for the convenience of the Examiner.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number set forth below.

Respectfully submitted,



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